[1662/50302]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Ayalon, et al.

Serial No.: 09/714,351

Filing Date: November 16, 2000

For: POLYMORPHIC FORM OF ATORVASTATIN CALCIUM

Group Art Unit: 1626

Examiner: Stockton

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop: Petition
Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
on
Date: February 28, 2007
Signature: Naomi Holliday
Naomi Holliday

TRANSMITTAL FOR PETITION UNDER 37 C.F.R. §§ 113(a) and 1.181(a)(1)

SIR:

Transmitted herewith is a Petition under 37 C.F.R. §§ 113(a) and 1.181(a)(1) in connection with the above-captioned application.

Please note additionally enclosed which accompany this response are the following:

Exhibits A through G.

It is believed that no fees are required in connection with this Petition. However, if any fees are required in connection with this Petition, the Commissioner is hereby authorized to charge any and all such fees to the deposit account of KENYON & KENYON LLP, Deposit Account No. 11 0600. A duplicate copy of this transmittal letter is enclosed for that purpose.

Respectfully submitted,

Dated: February 28, 2007

By: Joseph A Coppola
Joseph A. Coppola
Reg. No. 38,413

KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200 (telephone)
(212) 425-5288 (facsimile)
CUSTOMER NO. 26646

Docket No.: 1662/50302

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	Ayalon, et al.
SERIAL NO.	:	09/714,351
FILED	:	November 16, 2000
FOR	:	POLYMORPHIC FORM OF ATORVASTATIN CALCIUM
EXAMINER:		Stockton
GROUP ART UNIT	:	1626

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Date: February 28, 2007

Signature: Naomi Holliday

Naomi Holliday

Mail Stop Petition
COMMISSIONER FOR PATENTS
P.O. BOX 1450
Alexandria, VA 22313-1450

PETITION UNDER 37 C.F.R. §§ 113(a) and 1.181(a)(1)

SIR:

Petitioner requests that the objection to claims 1, 3-6, 16, and 17 as being substantial duplicates of claim 2 be withdrawn.

Background

In the Office Action dated May 4, 2006, a copy of which is Exhibit A, claims 1, 3-6, 16, and 17 were objected to as being substantial duplicates of claim 2. A copy of claims 1-6, 16, and 17 is Exhibit B.

The Applicants presented arguments against this objection in the Amendment filed October 4, 2006, a copy of which is Exhibit C.

The objection was maintained in the Office Action containing a final rejection dated December 29, 2006, a copy of which is Exhibit D.

Thus, this Petition is timely since it is being filed within two months of the December 29, 2006 mailing date of Exhibit D.

The merits of the objection

In support of the objection, Exhibit D stated, at page 4:

> In response, Applicant discloses in the instant specification and claims one crystalline form of a compound. Although the description of the one crystalline form in claims 1, 3-6, 16 and 17 is not as detailed as in claim 2, claims are all directed to a single crystalline form, i.e. Form V. Further, since no other ingredient is recited in the pharmaceutical composition of claim 16, the claim reads on just Form V. Therefore, claims 1, 3-6, 16 and 17 are directed to the same product as found in claim 2 and hence, are duplicates of claim 2.

The Applicants respectfully traverse this objection. An applicant has the right to claim an invention in a reasonable number of ways. *See In re Chandler*, 319 F.2d

211, 225, 138 U.S.P.Q. 138, 148 (CCPA 1963): "[A]pplicants should be allowed reasonable latitude in stating their claims in regard to number and phraseology employed. The right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."

The Applicants right to claim the invention in a reasonable number of ways includes the right to use different terminology to define the exact same subject matter. See, e.g., *Curtiss-Wright Flow Control Corp. v. Velan, Inc.*, 438 F. 3d 1374, 1380, 77 U.S.P.Q. 2d 1988, 1993-1994 (Fed. Cir. 2006):

> Different claims with different words can, of course, define different subject matter within the ambit of the invention. On the other hand, claim drafters can also use different terms to define the exact same subject matter. Indeed this court has acknowledged that two claims with different terminology can define the exact same subject matter. [underscoring added]

The applicant's right to claim an invention in a reasonable number of ways is especially strong in the case of claims to crystalline forms since the characterization of crystalline forms requires complicated analyses by such techniques as PXRD, single crystal X-ray diffraction, infrared spectroscopy, and raman spectroscopy. Small, inevitable uncertainties in the measurements produced by these techniques require that the applicant be granted latitude in the choice of language in order for the applicant to have a fair opportunity to properly capture the invention in the claims.

Thus, even if claims 1-6, 16, and 17 were directed to exactly the same subject matter, i.e., had exactly the same scope, the Applicants should be permitted to maintain claims 1-6, 16, and 17 in the present application. This is especially so for claims 2-5 and 17 because claims 2-5 and 17 are independent claims. *See Curtiss-Wright,* 438 F. 3d at 1380-1381, 77 U.S.P.Q. 2d at 1994: "It is not unusual that separate claims may define the invention using different terminology, especially

where (as here) independent claims are involved." (quoting *Hormone Research Found. v. Genentech, Inc.*, 904 F.2d 1558, 1567, n.15, 15 U.S.P.Q. 2d 1039, n.15 (Fed. Cir. 1990).

An additional consideration argues that claims 1-6, 16, and 17 should not be objected to as substantial duplicates. M.P.E.P. §706.03(k) states that "mere difference in scope between claims has been held to be enough" to prevent claims from being considered substantial duplicates).

Each of pending claims 1, 3-6, 16, and 17 differs in scope from claim 2. In determining the scope of the claims, the Office Action is ignoring the plain language of the claims and is looking beyond the claims to something outside the language of the claims ("[The] claims are all directed to a single crystalline form, i.e. Form V."). In reaching this conclusion about the scope of the claims, the Office Action ignores the different language used by the different claims ("Although the description of the one crystalline form in claims 1, 3-6, 16 and 17 is not as detailed as in claim 2 ...") and the different scopes thereby conferred on the claims by their use of different language. This is improper. It is settled law that the language of the claims determines the scope of the claims. See, .e.g., *Home Diagnostics, Inc. v. Lifescan, Inc.*, 381 F. 3d 1352, 1355, 72 U.S.P.Q. 2d 1276, 1278 (Fed. Cir. 2004) "[T]he claim language itself governs the meaning of the claim;" *Vitronics Corp. v. Conceptronic, Inc.,*, 90 F.3d at 1582, 39 U.S.P.Q. 2d 1573, 1576 (Fed. Cir. 1996): "[W]e look to the words of the claims themselves ... to define the scope of the patented invention."

Focusing on the words used in the claims leads to a conclusion that each of claims 1, 3-6, 16, and 17 differs in scope from claim 2. While all of the claims are directed to a particular crystalline form of atorvastatin, the scope of coverage of that crystalline form varies according to the language used in each claim. Claim 2 is

directed to a crystalline form of atorvastatin that must have an X-ray powder diffractogram substantially as that of the diffractogram depicted in claim 2. In contrast, none of claims 1, 3-6, 16, and 17 use language referring to the diffractogram depicted in claim 2. Thus, none of these claims require that the crystalline forms claimed have a diffractogram substantially as depicted in claim 2. Furthermore, different proofs would be required for claim 2 and for each of claims 1, 3-6, 16, and 17 in order to determine if a particular crystalline form of atorvastatin falls within the scope of those claims. These considerations indicate that there is a difference in scope between claim 2 and each of claims 1, 3-6, 16, and 17.

Furthermore, all of the claims differ in scope because it is necessary to satisfy different limitations to fall within the scope of each claim. Claim 1 requires that the claimed crystalline form be prepared by a certain process. Claim 2 requires that the claimed crystalline form have a PXRD substantially as in the depicted diffractogram. Claim 3 requires three particular PXRD peaks, with one of the peaks having a maximum at a certain position. Claim 4 requires a certain ^{13}C NMR spectrum. Claim 5 requires specific NMR signals. Claim 6 requires a certain water content. Claim 16 is directed to a pharmaceutical composition comprising a therapeutic amount of the claimed crystalline form. Claim 17 requires a combination of PXRD peaks and NMR signals.

Moreover, the Office Action is incorrect in its view that an application may contain only one claim to a crystalline form. In *Ex parte Gring*, 158 U.S.P.Q. 109 (Pat. & Tr. Office Bd. App. 1967), claims 1 and 5 read as follows:

> 1. A novel boehmite alumina product with particles of irregular edges, a pore structure totalling at least about 0.5 cc. per gram in pores larger than 80(Å) in size, an average crystallite size greater than about 40(Å), up to about 200(Å) by X-ray diffraction and composed of a non-homogeneous integral aggregation of polycrystalline boehmite sub-

units, said particles having a largest dimension of at least about 500(Å) by electron microscope.

5. The product of claim 1 which is that crystallographically depicted in Figure 1.

158 U.S.P.Q. at 110.

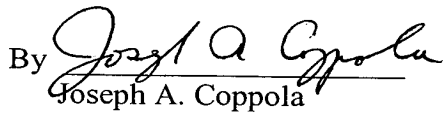
The Examiner had found that claim 5 was a substantial duplicate of claim 1. The Board of Appeals reversed this finding.

The holding of *Gring* is reinforced by the fact that the U.S. Patent & Trademark Office routinely grants patents containing more than one claim to a particular polymorph. See, e.g., U.S. Patent No. 6,900,221 (Exhibit E); U.S. Patent No. 6,903,106 (Exhibit F); and U.S. Patent No. 7,148,231 (Exhibit G).

In view of the above, an objection of claims 1, 3-6, 16, and 17 as being substantial duplicates of claim 2 is improper and it is requested that this objection be withdrawn.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

By 
Joseph A. Coppola
Reg. No. 38,413

Dated: February 28, 2007

KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200 (telephone)
(212) 425-5288 (facsimile)
CUSTOMER NUMBER 26646

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,351	11/16/2000	Ari Ayalon	1662/50302	6513

26646 7590 05/04/2006

KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
STOCKTON, LAURA LYNNE	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/714,351	AYALON ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *7-15,18 and 19* is/are withdrawn from consideration.

5)☒ Claim(s) *2* is/are allowed.

6)☒ Claim(s) *1, 3-6,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/3/06&2/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in the application.

Election/Restrictions

Applicants' election without traverse of Group I in the response filed February 24, 2004 was acknowledged in a previous Office Action. The requirement was deemed proper and made FINAL in a previous Office Actions.

Claims 7-15, 18 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the response filed February 24, 2004.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants'

amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on February 3, 2006 and February 27, 2006.

Claim Objections

Claims 1, 3-6, 16 and 17 are objected to for being substantial duplicate of claim 2. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. §706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 6, 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No support in the claims or the originally filed specification can be found for the phrase "diffraction peaks at 5.5 and 8.3 degrees 2θ" in currently amended claims 3 and 17. Applicants state that support is found for this amendment on page 5, lines 14-15. However, page 5, lines 14-15 state, "medium peaks at

5.3±0.2 and 8.3±0.2 degrees 2θ." Therefore, the claims lack written description as such.

Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,

5. the presence or absence of working examples,

6. the breadth of the claims,

7. the quantity of experimentation needed, and

8. the level of the skill in the art.

The nature of the invention

The nature of the invention is pharmaceutical compositions comprising Atorvastatin Form V or a hydrate thereof.

The state of the prior art

The state of the prior art is that it is known that many compounds exist in more than one crystalline form (polymorphs). Polymorphs exist in more stable and less stable (metastable) forms. The preparation of the pharmaceutical compositions requires creating solutions, milling, adding diluents, excipients, surfactants, etc. The process of preparing a pharmaceutical composition will cause a specific crystalline form, if in the metastable state, to resort

back to the most thermodynamically stable form, which is the form with the lowest vapor pressure. Polymorphs tend to convert from less stable to more stable forms (Rouhi, Chemical and Engineering News, February 24, 2003, pages 32-35, especially page 32). Drug companies must monitor the polymorph in the drug product to ensure that it persists during manufacture (Rouhi, page 34).

It is also the state of the prior art that an acceptable carrier for a pharmaceutical formulation can be water. Dissolving a specific crystalline form in water, creating an aqueous solution, would put the compound in its free form, and not in a crystalline form, with a specific X-ray diffraction pattern.

The predictability or lack thereof in the art

The predictability or lack thereof in the art is that a metastable compound will resort back into its most thermodynamically stable form which would have a different X-ray diffraction pattern and also that a

solution prepared from a specific crystalline form and water would contain the free form of the compound.

The amount of direction or guidance present and the presence or absence of working examples

While the specification has provided processes for the preparation of the Form V (see Example 1, for instance, on pages 13-14) and generic processes for preparing pharmaceutical compositions on pages 11-13, the specification fails to provide the steps of ensuring that the pharmaceutical compositions will maintain the specific forms as found in the specification and will not resort back to the free form or the most thermodynamically stable form of the compound.

The breadth of the claims

The breadth of the claims embraces a pharmaceutical composition comprising a therapeutic amount of atorvastatin Form V or hydrates thereof.

The quantity of experimentation needed

One of ordinary skill in the art would be unable to maintain a specific metastable crystalline form upon preparation into a pharmaceutical composition which may require milling or the formation of a solution. Therefore, the quantity of experimentation needed is undue.

The level of the skill in the art

While the level of skill in the art is high, one of ordinary skill in the art would be unable to maintain a specific metastable crystalline form upon the preparation of a pharmaceutical composition without direction and guidance that is not found in the instant specification. One of skill in the art would expect the pharmaceutical composition to contain the free form of the compound or the most thermodynamically stable form.

Response to Arguments

Applicants' arguments filed February 3, 2006 have been fully considered. Applicants argue that the plain meaning of the language of claim 16 is being ignored and that claim 16 is not being interpreted in a reasonable manner in light of the specification. Applicants argue that the stability argument is based on limitations that are not present in claim 16 by requiring that the pharmaceutical composition defined by claim 16 must contain crystalline Form V for some unspecified time, contain some unspecified proportion of crystalline Form V and/or be prepared by some particular process.

All of Applicants' arguments have been considered but have not been found persuasive. Instant claim 16 is directed to a pharmaceutical composition that is a solid or suspension comprising atorvastatin calcium Form V or hydrates thereof. In the instant specification on page 12, solid compositions and liquid

suspensions are discussed. As stated above, the preparation of the pharmaceutical compositions requires creating solutions, milling, adding diluents, excipients, surfactants, etc. Applicants have not shown that any of the atorvastatin calcium Form V or hydrates thereof would be present after undergoing a process such as milling in making a solid composition such as a tablet for a pharmaceutical use. Applicants have not disclosed any other process in making a solid composition. Therefore, Applicants' arguments are not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention.

Claims 1, 3-6, 16 and 17 are rejected for being substantial duplicates of claim 2.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Briggs et al. {WO 97/03959} or McKenzie et al. {WO 97/03958}.

Briggs et al. disclose, for example Form II, which has X-ray power diffraction patterns (see pages 5-6) and ^{13}C nuclear magnetic resonance chemical shifts (see

page 7) embraced by the instant claimed invention (see especially instant claims 3 and 5).

McKenzie et al. disclose Form III, which has X-ray power diffraction patterns (see page 4) and ^{13}C nuclear magnetic resonance chemical shifts (see page 5) embraced by the instant claimed invention (see especially instant claims 3 and 5).

Response to Arguments

Applicants' arguments filed February 3, 2006 have been fully considered. Applicants argue the differences between the X-ray power diffraction patterns and ^{13}C nuclear magnetic resonance chemical shifts in each of the cited references. In response, because of the processing required to make a solid composition, the pharmaceutical composition will contain other forms of atorvastatin calcium. See the instant specification on pages 13, lines 4-6. Applicants' arguments state, "claim 16 does not contain

any limitations with respect to the crystalline forms maintaining their structure for any particular length of time." (page 11 of Remarks section). Therefore, claim 16 is anticipated by the cited prior art.

Allowable Subject Matter

Claim 2 is allowed over the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact

the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

May 1, 2006

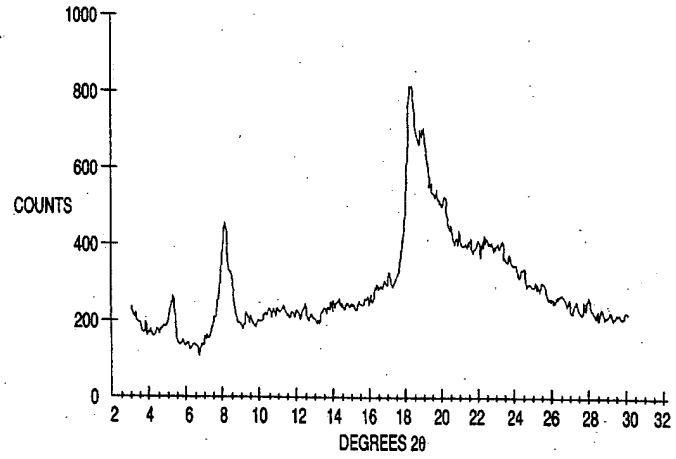
1. Atorvastatin calcium Form V or hydrate thereof of claim 3 produced by a process comprising the steps of

   a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution,

   b) contacting the atorvastatin salt solution with a calcium salt, and

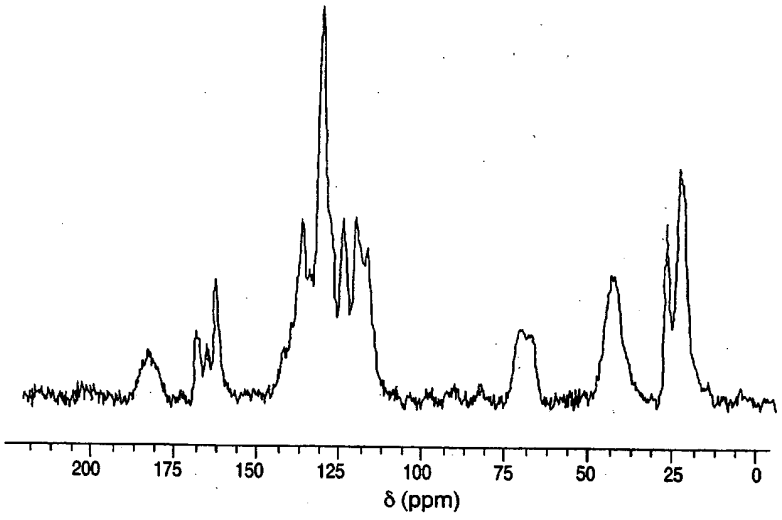
   c) isolating crystalline atorvastatin calcium Form V or hydrate thereof.

2. Atorvastatin calcium Form V or hydrate thereof having an X-ray powder diffractogram substantially as follows



3. Atorvastatin calcium Form V and hydrates thereof characterized by X-ray powder diffraction peaks at 5.3 ±0.2 and 8.3 ±0.2 degrees 2θ and a broad peak at 18-23 +/- 0.2 degrees 2θ with a maximum at 18.3 +/- 0.2 degrees 2θ.

4. Atorvastatin calcium Form V or hydrate thereof having a solid state ^{13}C NMR spectrum substantially as follows



5. Atorvastatin calcium Form V and hydrates thereof characterized by solid state ^{13}C NMR signals at 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

6. Atorvastatin calcium Form V of claim 3 containing up to about 9 moles of water per mole of atorvastatin calcium.

16. A pharmaceutical composition that is a solid or suspension comprising a therapeutic amount of atorvastatin calcium Form V or hydrates thereof of claim 1, 3, or 5.

17. Atorvastatin calcium Form V and hydrates thereof characterized by x-ray powder diffraction peaks at 5.3 ±0.2 and 8.3 +/- 0.2 degrees 2θ and ^{13}C NMR signals at 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

Docket No.: 1662/50302

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT	:	Ayalon et al.
SERIAL NO.	:	09/714,351
FILED	:	November 16, 2000
FOR	:	POLYMORPHIC FORM OF ATORVASTATIN CALCIUM
EXAMINER:		Stockton
GROUP ART UNIT	:	1626

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

Date: October 24, 2006

Signature: Noemi Kolodny

COMMISSIONER FOR PATENTS
P.O. BOX 1450
Alexandria, VA 22313-1450

AMENDMENT

SIR:

In response to the Office Action dated May 4, 2006, please consider the following amendments and remarks. Enclosed herewith is a Petition for the Extension of Time.

CLAIM AMENDMENTS

This listing of claims will replace all prior versions and listings of claims in the application:

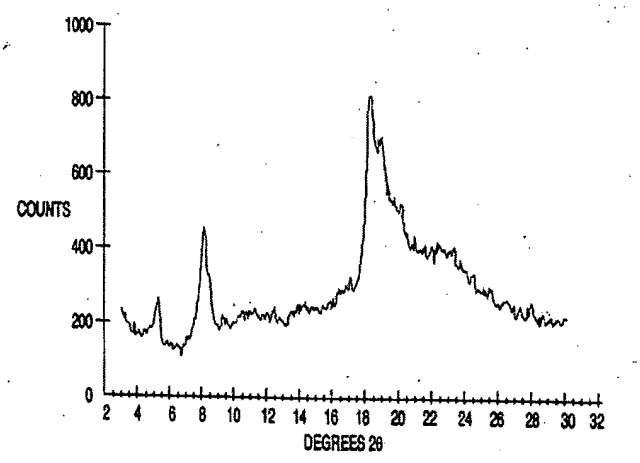
1. (previously presented) Atorvastatin calcium Form V or hydrate thereof of claim 3 produced by a process comprising the steps of

   a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution,

   b) contacting the atorvastatin salt solution with a calcium salt, and

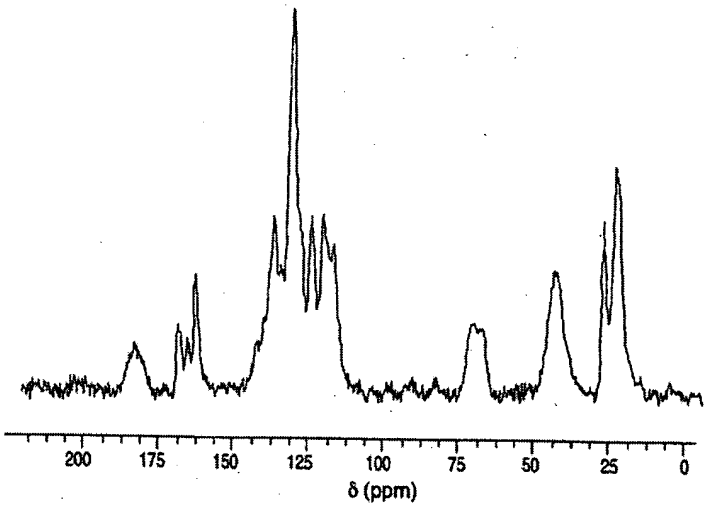
   c) isolating crystalline atorvastatin calcium Form V or hydrate thereof.

2. (previously presented) Atorvastatin calcium Form V or hydrate thereof having an X-ray powder diffractogram substantially as follows



3. (currently amended) Atorvastatin calcium Form V and hydrates thereof characterized by X-ray powder diffraction peaks at ~~5.5~~ 5.3 ±0.2 and 8.3 ±0.2 degrees 2θ and a broad peak at 18-23 +/- 0.2 degrees 2θ with a maximum at 18.3 +/- 0.2 degrees 2θ.

4. (previously presented) Atorvastatin calcium Form V or hydrate thereof having a solid state ^{13}C NMR spectrum substantially as follows



5. (previously presented) Atorvastatin calcium Form V and hydrates thereof characterized by solid state ^{13}C NMR signals at 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

6. (previously presented) Atorvastatin calcium Form V of claim 3 containing up to about 9 moles of water per mole of atorvastatin calcium.

7. (withdrawn) A process for preparing atorvastatin calcium Form V and hydrates thereof of either of claims 3 or 5, comprising the steps of

a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution

b) contacting the atorvastatin salt solution with a calcium salt, and

c) isolating atorvastatin calcium Form V or hydrates thereof.

8. (withdrawn) The process of claim 7 wherein the salt of atorvastatin is a metal salt of atorvastatin.

9. (withdrawn) The process of claim 8 wherein the metal salt of atorvastatin is a sodium salt of atorvastatin.

10. (withdrawn) The process of claim 7 wherein the calcium salt is calcium acetate.

11. (withdrawn) The process of claim 7 wherein the calcium salt is dissolved in a solvent and the atorvastatin salt solution is contacted with the calcium salt by adding the calcium salt solution to the atorvastatin salt solution.

12. (withdrawn) A process for preparing atorvastatin calcium Form V or hydrates thereof of either of claims 3 or 5, comprising the steps of

a) dissolving atorvastatin calcium in a solvent selected from the group consisting of tetrahydrofuran and hydroxylic solvents to form an atorvastatin calcium salt solution,

b) adding water to the atorvastatin calcium salt solution, and

c) isolating atorvastatin calcium Form V or hydrates thereof.

13. (withdrawn) The process of claim 12 wherein the solvent is methanol.

14. (withdrawn) The process of claim 12 wherein the solvent is ethanol.

15. (withdrawn) The process of claim 12 wherein the solvent is tetrahydrofuran.

16. (previously presented) A pharmaceutical composition that is a solid or suspension comprising a therapeutic amount of atorvastatin calcium Form V or hydrates thereof of claim 1, 3, or 5.

17. (currently amended) Atorvastatin calcium Form V and hydrates thereof characterized by x-ray powder diffraction peaks at ~~5.5~~ 5.3 ±0.2 and 8.3 +/- 0.2 degrees 2θ and ^{13}C NMR signals at 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

18. (withdrawn) A method of making atorvastatin calcium Form V of claim 2 or 4 and hydrates thereof comprising the steps of:

a) dissolving a metal, ammonium or alkylammonium salt of atorvastatin in a solvent to form an atorvastatin salt solution

b) contacting the atorvastatin salt solution with a calcium salt, and

c) isolating atorvastatin calcium Form V or hydrate thereof.

19. (withdrawn) A method of making atorvastatin calcium Form V or hydrate thereof of either of claims 2 or 4, comprising the steps of:

a) dissolving atorvastatin calcium in a solvent selected from the group consisting of tetrahydrofuran and hydroxylic solvents to form an atorvastatin calcium salt solution,

b) adding water to the atorvastatin calcium salt solution, and

c) isolating ~~the~~ atorvastatin calcium Form V or hydrate thereof.

REMARKS

Claims 1-19 are pending.

Claims 7-15, 18, and 19 have been withdrawn from consideration.

By this Amendment, claim 3 has been amended to recite "peaks at 5.3 ±0.2 and 8.3 ±0.2 degrees 2θ." Claim 17 has been similarly amended. Support for these amendments is found in the specification at page 5, lines 14-15.

The Applicants thank the Examiner for indicating that claim 2 is allowed.

Claim objections

Claims 1, 3-6, 16, and 17 were objected to as being substantial duplicates of claim 2.

M.P.E.P. §706.03(k) states that "mere difference in scope between claims has been held to be enough" to prevent claims from being considered substantial duplicates. Here all of claims 1, 3-6, 16, and 17 differ in scope from claim 2. Claim 2 is directed to a crystalline form of atorvastatin that must have an X-ray powder diffractogram substantially as that of the diffractogram depicted in claim 2. In contrast, none of claims 1, 3-6, 16, and 17 require that the crystalline forms claimed have the diffractogram depicted in claim 2. This alone provides for a difference in scope between claim 2 and each of claims 1, 3-6, 16, and 17 and leads to the conclusion that an objection of claims 1, 3-6, 16, and 17 as being substantial duplicates of claim 2 is improper.

Court decisions have upheld an applicant's right to claim an invention in a reasonable number of ways. *See In re Flint*, 411 F.2d 1353, 1357 (C.C.P.A. 1969) ("applicants should be allowed reasonable latitude in stating their claims in regard to

number and phraseology employed."); *In re Chandler*, 319 F.2d 211, 225 ("[t]he right of applicants to freedom of choice in selecting phraseology which truly points out and defines their inventions should not be abridged."). In order to support the present objection, the Office Action must "set forth typical examples of substantial duplication or lack of material differentiation, discuss[ed] the relative complexity of the invention, allege[d] a lack of difference in scope of the claims, and refer[red] to representative prior art." *In re Flint*, 411 F.2d at 1356-1357.

The Office Action has done none of this. There has been no analysis along the lines required by *In re Flint*. There has been no analysis to demonstrate that the number of ways the Applicants have claimed their invention is unreasonable or that the claims objected to are of the same scope as allowed claim 2. The entirety of the Office Action directed to this objection reads as follows:

> Claims 1, 3-6, 16 and 17 are objected to for being substantial duplicate [sic] of claim 2. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim.
>
> Office Action, page 3, lines 8-15.

Thus, there is no reasoned analysis at all in support of this objection.

In view of the above, it is respectfully requested that this objection be withdrawn.

The rejection under 35 U.S.C. §112

Claims 1, 3, 6, 16, and 17 were rejected for lack of written description.

Claims 3 and 17 have been amended to recite "5.3 ±0.2 and 8.3 ±0.2 degrees 2θ." Accordingly, it is respectfully requested that this rejection be withdrawn.

Claim 16 was rejected for lack of enablement.

This rejection relies on two premises: (1) metabstable crystalline forms tend to convert to the most stable form; and (2) the usual procedures used to prepare pharmaceutical compositions (grinding, milling, adding excipients, etc.) will convert a metastable form to a stable form.

The Applicants traverse this rejection because no evidence supporting the second premise has been provided.

The only evidence cited in support of this rejection is Rouhi Chemical and Engineering News, February 24, 2003, pages 32-35. Rouhi at most shows that metastable forms tend to, i.e., may possibly, convert to the most thermodynamically stable form. See the Office Action, page 7, lines 2-5: "Polymorphs tend to convert from less stable to more stable forms (Rouhi, Chemical and Engineering News, February 24, 2003, pages 32-35, especially page 32)."

The specification teaches that Form V can be formulated into pharmaceutical compositions. See page 10, line 19 to page 13, line 3. Thus, the specification teaches that Form V will persist after being formulated into pharmaceutical compositions. The burden is on the USPTO to provide evidence or reasoning, not just mere speculation, as to why this teaching of the specification is incorrect. See *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971), where the United States Court of Customs and Patent Appeals stated:

> [A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein .... [emphasis in original]
>
> 439 F.2d at 223, 169 U.S.P.Q. at 369.

> [I]t is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. [italics in original; underscoring added]
>
> 439 F.2d at 224, 169 U.S.P.Q. at 370.

The Office Action has not met this burden. A premise of this rejection is that Form V will not persist upon being formulated into a pharmaceutical composition. This goes far beyond the evidence that the Office Action has cited in support of this rejection. The cited evidence (Rouhi) at most shows that metastable forms may possibly convert to the most thermodynamically stable form. The cited evidence says nothing about the likelihood, the speed of, or the completeness of, such a conversion.

There is nothing in Rouhi that supports the proposition that Form V is likely to convert so rapidly and so completely into the most stable form when formulated into a pharmaceutical composition that a person skilled in the art could not practice the invention defined in claim 16. Nor was any other evidence provided to support such a proposition.

The only reason given in the Office Action for such a proposition is the speculation that if Form V is subjected to the usual procedures for making pharmaceutical compositions it will convert to other forms. See, e.g., the Office Action, page 6, line 13 to page 7, line 2:

> The preparation of he pharmaceutical compositions requires creating solutions, milling, adding diluents, excipients, surfactants, etc. The process of preparing a pharmaceutical composition will cause a specific crystalline from, if in the metastable state, to resort back to the most thermodynamically stable form, which is the form with the lowest vapor pressure. [underscoring added]

The key portion of the above passage is the underlined quote. This quote expresses the second premise underlying this rejection. The Office Action provided no evidence in support of this quote.

Furthermore, Rouhi teaches that the second premise underlying this rejection is wrong. Rouhi teaches that the likely outcome of formulation of a crystalline form, when carried out by those skilled in the art, is that the crystalline form used would maintain itself for a reasonable period of time such that the pharmaceutical composition would be useful. This is implicit in Rouhi since one of the main themes in Rouhi is that pharmaceutical companies are actively seeking new crystalline forms of compounds (even metastable forms) in order to formulate these crystalline forms into pharmaceutical compositions (see page 32, right column; "[M]uch effort is being expended looking for metastable forms of currently marketed drugs whose stable forms have been around for a long time." It would make no sense for pharmaceutical companies to behave in such a manner if the second premise underlying this rejection were correct.

Furthermore, conversion to the most stable form can be quite slow and less stable crystalline forms can co-exist with the most stable crystalline form. See U.S. Pharmacopia #23, National Formulary #18 (1995), page 1843, entry (941), X-Ray Diffraction[1]:

> Many compounds are capable of crystallizing in more than one type of crystal lattice. At any particular temperature and pressure, only one crystalline form (polymorph) is thermodynamically stable. Since the rate of phase transformation of a metastable polymorph to the stable one can be quite slow, it is not uncommon to find several polymorphs of crystalline pharmaceutical compounds existing under normal handling conditions.

[1] A copy of this reference was provided with the Information Disclosure Statement that was filed on February 16, 2006..

The quotation above shows that the second premise underlying this rejection ignores the fact that, even if conversion to a more stable form occurs, that conversion may be "quite slow." In fact, this quotation implies that such "quite slow" conversion is "not uncommon." Thus, the evidence of record indicates that the likely outcome of formulating Form F into pharmaceutical compositions is that Form F will persist, at least for a period of time sufficient to provide a useful pharmaceutical composition.

In view of the above, it can be seen that the evidence provided in the Office Action is inadequate to support this rejection. Thus, the Office Action failed to provide "acceptable evidence or reasoning" to support the rejection, as required by *Marzocchi.*

The Office Action reads claim 16 as including solutions of Form V where the pharmaceutically acceptable carrier is water. See the Office Action, page 7, lines 9-14. The Applicants note that claim 16 is directed to a pharmaceutical composition "that is a solid or suspension." In view of this, it is respectfully requested that this aspect of the rejection is improper. Thus, the Office Action's reading of claim 16 is incorrect.

The Applicants believe that the above discussion demonstrates that claim 16 does not lack enablement. In view of the above, it is respectfully requested that this rejection be withdrawn.

Claims 1, 3, 6, 16, and 17 were rejected for indefiniteness.

This rejection is based on the premise that claims 1, 3, 6, 16, and 17 are substantial duplicates of claim 2. As discussed above, this is incorrect. Accordingly, it is respectfully requested that this rejection be withdrawn.

The rejection under 35 U.S.C. §102(b)

Claim 16 was rejected as being anticipated by International Patent Publications WO 97/03959 (Briggs) or WO 97/03958 (McKenzie).

The Office Action stated that Briggs disclosed Form II atorvastatin, which has X-ray powder diffraction patterns and ^{13}C NMR chemical shifts "embraced by the instant claimed invention (see especially instant claims 3 and 5)." (Office Action, page 13, lines 1-2).

Claim 16 depends from claim 1, 3, or 5. Thus, if Briggs does not anticipate claim 1, 3, or 5, Briggs does not anticipate claim 16.

Claim 3 has been amended to require a PXRD peak at 5.3 ±0.2 degrees 2θ (i.e., between 5.1-5.5 degrees 2θ), a PXRD peak at 8.3 ±0.2 degrees 2θ (i.e., between 8.1-8.5 degrees 2θ), and a broad peak at 18-23 ±0.2 degrees 2θ with a maximum at 18.3 ±0.2 degrees 2θ (i.e., a broad peak between 17.8-23.2 degrees 2θ with a maximum at 18.1-18.5 degrees 2θ).

Form II of Briggs does not meet these limitations of amended claim 3 because Form II does not have a peak between 5.1-5.5 degrees 2θ or a peak between 8.1-8.5 degrees 2θ. Form II also does not have a broad peak between 17.8-23.2 degrees 2θ with a maximum at 18.1-18.5 degrees 2θ. See the table on page 6 of Briggs (reproduced below), which shows the PXRD peaks of Form II.

2θ	d	Relative Intensity (>20%) Ground 2 Minutes
5.582	15.8180	42.00
7.384	11.9620	38.63
8.533	10.3534	100.00
9.040	9.7741	92.06
12.440 (broad)	7.1094	30.69
15.771 (broad)	5.6146	38.78
17.120-17.360 (broad)	5.1750-5.1040	63.66-55.11
19.490	4.5507	56.64
20.502	4.3283	67.20
22.706-23.159 (broad)	3.9129-3.8375	49.20-48.00
25.697 (broad)	3.4639	38.93
29.504	3.0250	37.86

Thus, Briggs does not anticipate claim 3.

Claim 1 depends from claim 3. Thus, Briggs does not anticipate claim 1.

Claim 5 requires a ^{13}C NMR spectrum characterized by signals at 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

Form II of Briggs does not meet these limitations of claim 5 because Form II does not have any of these signals, with the exception of the signal at 161.0 ppm. See the table on page 7 of Briggs (reproduced below), showing the ^{13}C NMR signals of Form II.

Assignment	Chemical Shift
Spinning Side Band	209.1
Spinning Side Band	206.8
C12 or C25	181 (broad)
C12 or C25	163 (broad)
C16	161 (broad)
Aromatic Carbons	
C2-C5, C13-C18, C19-C24, C27-C32	140.5
	134.8
	133.3
	129.0
	122.9
	121.4
	120.3
	119.0
	117.1
	115.7
	114.7
C8, C10	70.6
	69.0
	68.0
	67.3
Spinning Side Band	49.4
Spinning Side Band	48.9
Methylene Carbons	
C6, C7, C9, C11	43.4
	42.3
	41.7
	40.2
C33	27.5
C34	22.8 (broad)

Thus, Briggs does not anticipate claim 5.

Since Briggs does not anticipate any of claims 1, 3, or 5, Briggs does not anticipate claim 16.

The Office Action stated that McKenzie disclosed Form III atorvastatin, which has X-ray powder diffraction patterns and ^{13}C NMR chemical shifts "embraced by the instant claimed invention (see especially instant claims 3 and 5)." (Office Action, page 13, lines 6-7).

Claim 3 has been amended to require a PXRD peak at 5.3 ±0.2 degrees 2θ (i.e., between 5.1-5.5 degrees 2θ), a PXRD peak at 8.3 ±0.2 degrees 2θ (i.e., between 8.1-8.5 degrees 2θ), and a broad peak at 18-23 ±0.2 degrees 2θ with a maximum at

18.3 ±0.2 degrees 2θ (i.e., a broad peak between 17.8-23.2 degrees 2θ with a maximum at 18.1-18.5 degrees 2θ).

Form III of McKenzie does not meet these limitations of amended claim 3 because Form III does not have a peak between 5.1-5.5 degrees 2θ. See the table on page 4 of McKenzie (reproduced below), showing the PXRD peaks of Form III.

2θ	d	Relative Intensity (>25%)
4.123	21.4140	49.20
4.993	17.6832	30.82
5.768	15.3099	28.69
7.670	11.5173	25.49
8.451	10.4538	100.00
15.962	5.5478	32.59
16.619	5.3298	62.34
17.731	4.9981	49.29
18.267	4.8526	45.12
18.870	4.6989	39.52
19.480	4.5531	36.59
19.984	4.4393	70.34
20.294	4.3722	69.54
21.105	4.2061	37.39
21.670	4.0976	36.50
23.318	3.8117	38.63
24.405	3.6442	65.54
24.967	3.5635	27.20
25.397	3.5041	33.75

Thus, McKenzie does not anticipate claim 3.

Claim 1 depends from claim 3. Thus, McKenzie does not anticipate claim 1.

Claim 5 requires a ^{13}C NMR spectrum characterized by signals at 21.9, 25.9, 118.9, 122.5, 128.7, 161.0 and 167.1 ppm.

Form III of McKenzie does not meet these limitations of claim 5 because Form III does not have any of these signals, with the exception of the signal at 161.0

ppm. See the table on page 5 of McKenzie (reproduced below), showing the ^{13}C NMR signals of Form III.

Assignment	Chemical Shift
Spinning Side Band	214.8
	209.3
	202.3
C12 or C25	184.9
C12 or C25	166.7
C16	161.0(weak, broad)
Aromatic Carbons	
C2-C5, C13-C18, C19-C24, C27-C32	140.1
	135.2
	131.8
	128.9
	124.3
	122.2
	117.2
	114.9
C8, C10	69.8
	67.3
	65.6
Methylene Carbons	
C6, C7, C9, C11	44.1
	40.4
	35.4
C33	27.0
	24.1
C34	22.1
	19.9

Thus, McKenzie does not anticipate claim 5.

Claim 16 depends from claim 1, claim 3, or claim 5. Since McKenzie does not anticipate claim 1, claim 3, or claim 5, McKenzie also does not anticipate claim 16.

In view of the above, it is respectfully requested that these anticipation rejections be withdrawn.

Withdrawn claims

The Applicants respectfully request rejoinder of the withdrawn claims.

Claims 7-15, 18, and 19 are process claims that depend from product claims 2-5. As discussed above, claims 2-5 are allowable. Therefore, rejoinder is proper.

The time for responding to the Office Action was set for August 4, 2006. Enclosed is a Petition for the Extension of Time under 37 C.F.R. § 1.136(a) for a period sufficient to permit the filing of this response.

The Applicants hereby make a Conditional Petition for any relief available to correct any defect seen in connection with this filing, or any defect seen to be remaining in this application after this filing. The Commissioner is authorized to charge Kenyon & Kenyon's Deposit Account No. 11-0600 for the Petition fee and any other fees required to effect this Conditional Petition.

Respectfully submitted,

By Joseph A Coppola

Dated: October 4, 2006

Joseph A. Coppola
Reg. No. 38,413

KENYON & KENYON LLP
One Broadway
New York, NY 10004
(212) 425-7200 (telephone)
(212) 425-5288 (facsimile)
CUSTOMER NUMBER 26646

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/714,351	11/16/2000	Ari Ayalon	1662/50302	6513

26646 7590 12/29/2006
KENYON & KENYON LLP
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER	
STOCKTON, LAURA LYNNE	
ART UNIT	**PAPER NUMBER**
1626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/714,351	AYALON ET AL.	
	Examiner	Art Unit	
	Laura L. Stockton, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on October 10, 2006.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) 7-15,18 and 19 is/are withdrawn from consideration.

5)☒ Claim(s) 2 is/are allowed.

6)☒ Claim(s) 1, 3-6,16 and 17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending in the application.

Election/Restrictions

Applicant's election without traverse of Group I in the response filed February 24, 2004 was acknowledged in a previous Office Action. The requirement was deemed proper and made FINAL in a previous Office Actions.

Claims 7-15, 18 and 19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Election was made **without** traverse in the response filed February 24, 2004.

Rejections made in the previous Office Action that do not appear below have been overcome by Applicants'

amendments to the claims. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Objections

Claims 1, 3-6, 16 and 17 are objected to for being substantial duplicate of claim 2. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a substantial duplicate of the allowed claim. M.P.E.P. §706.03(k).

Response to Arguments

Applicant's arguments filed October 10, 2006 have been fully considered but they are not persuasive. Applicant argues that none of claims 1, 3-6, 16 and 17

require that the crystalline forms claimed have the diffractogram depicted in claim 2.

In response, Applicant discloses in the instant specification and claims one crystalline form of a compound. Although the description of the one crystalline form in claims 1, 3-6, 16 and 17 is not as detailed as in claim 2, claims are all directed to a single crystalline form, i.e. Form V. Further, since no other ingredient is recited in the pharmaceutical composition of claim 16, the claim reads on just Form V. Therefore, claims 1, 3-6, 16 and 17 are directed to the same product as found in claim 2 and hence, are duplicates of claim 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 16 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-6, 16 and 17 are rejected for being substantial duplicates of claim 2.

Allowable Subject Matter

Claim 2 is allowed over the art of record.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 7-15, 18 and 19 drawn to an invention nonelected without traverse in the reply filed February 24, 2004. A complete reply to the final rejection must include cancellation of

nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

December 26, 2006

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